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SECTION 6: 510(k) SUMMARY

NOV 10 2011

Date of Preparation: September 28, 2011

Company Name / Contact:

Company: Compression Therapy Concepts, Inc.
35 James Way
Eatontown, NJ 07724-2272

Contact: Leonard Nass
Phone: (732) 544-0800
Fax: (732) 544-0850
LNass@ctcdvt.com

Establishment Registration Number: 2249552

Device Identification:

Proprietary Name:	VasoPress Reprocessed DVT Garment
Common Used Name:	Compressible Limb Sleeve
Classification Reference:	21 CFR § 870.5800
Classification Panel:	Cardiovascular
Device Product Code:	JOW
Proposed Regulatory Class:	Class II

Predicate Device:

The VasoPress Reprocessed DVT Garments are substantially equivalent to devices in commercial distribution by Compression Therapy Concepts, Inc., 35 James Way, Eatontown, NJ 07724. Specifically the VasoPress DVT Leg Garments VP 501 (K991038) and VasoPress DVT Foot Garments VP 520 (K003828).

Device Description:

The VasoPress Reprocessed DVT Leg Garment consists of a brushed nylon outer material bonded to a foam inner liner bonded to a tricot lining. An inflatable polyvinylchloride (PVC) pressure bag is encapsulated between an additional nylon/foam material. The VasoPress Reprocessed DVT Foot Garment has the same outer shell with a polyurethane (PU) pressure bag inside. An exit tube leads out from the pressure bag for connection to the VasoPress Pump. The device is automatically inflated by a pneumatic pump. The patient contact material is tricot over polyurethane foam. The reprocessed devices are cleaned, inspected and tested, packaged and exposed to Ethylene Oxide (EO) gas wash. The VasoPress Reprocessed DVT Garments are provided non-sterile.

Indications for Use:

The DVT Garment is an external pneumatic compression device intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.

This is the same intended use as previously cleared for the VasoPress DVT Garments under K991038 and K003828.

Technological Characteristics:
The VasoPress Reprocessed DVT Garments have the same technological characteristics as the predicate devices. The materials used in the garments are identical and the mode of operation is unchanged.

Performance Testing:
To demonstrate robust performance of VasoPress DVT garments after reprocessing, several performance tests were implemented:

- Bladder fatiguing (worst-case simulated use)
- Leak testing of the bladders
- Inflation / Deflation curve analysis of reprocessed versus new, unused VasoPress garments
- Velcro adhesion evaluation

Each of the above evaluations were performed after reprocessing and compared to garments that were not reprocessed to establish substantial equivalence. A detailed summary of performance test data is provided in Section 12 to this 510(k). The data demonstrates that reprocessed garments perform in a substantially equivalent manner to new, unused garments.

100% verification of bladder integrity is performed on reprocessed VasoPress garments by implementing the leak test whereby the bladders are pressurized to 240mmHg (twice the amount deliverable by the garment's pump) and allowed to dwell for thirty (30) seconds without a drop in pressure above 20 mmHg. This 100% testing of reprocessed VasoPress garments demonstrates that every garment is functional prior to release and is consistent with the manner of testing for new, unused devices.

Summary of Reprocessing:
Reprocessed VasoPress garments are exposed to a validated cleaning process based upon requirements for soil removal defined in AAMI TIR30. All garments are evaluated for end of life via 100% verification during the reprocessing cycle by leak testing of the garment bladder. Reprocessed VasoPress garments are clearly marked with an indicator that it has been reprocessed and the garments are packaged in an identical manner as new, unused garments. Garments are exposed to an EO wash as a final processing step.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 10 2011

Compression Therapy Concepts, Inc.
c/o Mr. Leonard Nass
Vice President
35 James Way
Eatontown, NJ 07724-2272

Re: K112838
VasoPress Reprocessed DVT Garment
Regulation Number: 21 CFR §870.5800
Regulation Name: Sleeve, Limb, Compressible
Regulatory Class: Class II
Product Code: JOW
Dated: September 27, 2011
Received: September 28, 2011

Dear Mr. Nass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112838

INDICATIONS FOR USE

510(k) Number (if known): K112838

Device Name: VasoPress Reprocessed DVT Garment

Indications for Use:

The DVT Garment is an external pneumatic compression device intended to lower the risk of deep vein thrombosis (DVT) and resulting pulmonary embolism (PE) in patients who may be at risk for thrombosis formation.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112838